Remarks

Claims 1 and 8 to 35 are pending and before the Examiner.

As a first matter, applicants wish to correct a typographical error in the prior Amendment dated September 15, 2006. In the first full paragraph on page 8, applicants stated "Furthermore, neither Harlan *et al.* (disclosing an aerosol formulation of statins), nor Bohm *et al.* (disclosing a combination of telmisartan with ACE inhibitors) do not disclose, suggest, or hint at telmisartan combinations with statins." (the "do not" is incorrect and nonsensical in light of the neither/nor construction of the sentence). This sentence should properly read "Furthermore, neither Harlan *et al.* (disclosing an aerosol formulation of statins) nor Bohm *et al.* (disclosing a combination of telmisartan with ACE inhibitors) disclose, suggest, or hint at telmisartan combinations with statins." Applicants regret any confusion this error may have caused and herewith correct the record.

The Examiner again rejected claims 1 and 8 to 17 as allegedly not enabled under 35 U.S.C. § 112, first paragraph.

In response, applicants again traverse the rejection as improper. "When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement". *In re Wright*, 27 U.S.P.Q. 1510, 1513 (Fed. Cir. 1993)(emphasis added). The Examiner alleges that the term "prevent" requires absolute success and that this is the "broadest reasonable interpretation". Applicants again maintain that this is an unreasonable interpretation of the meaning of prevention, is contrary to what one of ordinary skill in the art would understand "prevent" to mean in the context of the invention, and is accordingly improper. The Examiner refuses to follow the reasoning of *Ex parte Cho*, Appeal No. 2001-2646 (Bd. Pat. App. & Int. 2002)(nonprecidential), because each case is "unique" and involves "a distinctly different fact pattern". Of course every case is unique, but fundamental fairness requires that similar cases be decided similarly or the use of court cases and Board decisions to determine the proper outcome in a new case would be meaningless. The statement that "Logically, if the recited

compounds are useful for treating conditions such as pain and inflammation once they exist, they would also be expected to be effective in preventing pain and inflammation, if they were administered before the onset of pain or inflammation." (emphasis in original) is a generalized statement not limited to the specific technology of *Ex parte Cho*. Applicants have explained why *Ex parte Cho* is applicable to the instant case and its conclusion that compounds shown to be useful for treating conditions once they exist, would be expected to be effective in preventing these conditions if administered before the onset of the condition. The Examiner must explain what allegedly "distinctly different fact pattern" requires a different result than that reached in *Ex parte Cho*: conclusory statements that the situations are different without explaining why these alleged differences result in a different outcome does not meet the Examiner's obligation of providing reasoning for rejections. The Examiner cannot sit mum, leaving the applicant to shoot arrows into the dark hoping to somehow hit a secret objection harbored by the Examiner. *In re Oetiker*, 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992)(Plager, J., concurring). Examiners must state clearly and specifically any objections to patentability to establish the elements of a *prima facie* case and give the applicant fair opportunity to meet those objections with evidence and argument. *Id.* Furthermore, given that applicants have admitted on the record that "prevent" does not require absolute success, there is no possibility that the issued claims would be interpreted to require absolute success. Applicants again note that the Office has been repeatedly reversed for rejecting for lack of enablement claims directed to compounds having demonstrated pharmaceutical and biological activity. *See* M.P.E.P. § 2107 (particularly §§ 2107.01 III/IV and 2107.03, discussing the relationship of the utility and enablement requirements and the role of the FDA) and § 2164 (particularly § 2164.06). It is very likely that the Board would follow the reasoning of *Ex parte Cho* in the instant case. According, applicants respectfully request that the Examiner reconsider and withdraw the rejection.

The Examiner also rejected claims 1, 8, and 18 to 32 as allegedly anticipated under 35 U.S.C. § 102(b) over De Gasparo *et al.* (WO 01/76573), in light of Robl *et al.* (U.S. Patent Appl. Pub. No. 2002/0013334) cited to show a fact.

In response, applicants traverse the Examiner's rejection. De Gasparo *et al.* does not specifically disclose the specific combination of telmisartan and simvastatin anywhere and the Examiner has not pointed out how De Gasparo *et al.* thereby anticipates the claimed

invention. The teachings and statements in De Gasparo *et al.* must be considered in context and interpreted as a whole. De Gasparo *et al.*, at page 1, lines 27 to 29, cited by the Examiner does not represent the complete teaching of De Gasparo *et al.*, because the complete teaching at least also includes page 1, line 30, i.e., "(iii) an ACE inhibitor or a pharmaceutically acceptable salt thereof". De Gasparo *et al.* does not seem to give any preference to any particular combination within the broad disclosure, certainly not a specific combination of telmisartan and simvastatin. Indeed, De Gasparo *et al.*, at page 3, line 22, merely defines "AT_1 receptor antagonists" as including a number of commercially available sartans including telmisartan, but, contrary to the assertion of the examiner, telmisartan in De Gasparo *et al.* is not disclosed as a selected compound in the context of a specific combination, much less with simvastatin. The only sartan which is specifically mentioned in De Gasparo *et al.* in the context of a specific combination is valsartan. Similarly, in De Gasparo *et al.*, simvastatin is mentioned on page 5, lines 7 and 10, but is not mentioned in the context of a specific combination, much less with telmisartan. On page 5, line 27, and page 6, line 1, De Gasparo *et al.* teaches that simvastatin is a preferred or most preferred composition partner with valsartan (not telmisartan). De Gasparo *et al.* on page 6, lines 8 and 11 refer to the combination of statins such as simvastatin with ACE inhibitors (there is no analgous teaching with regard to AT_1 receptor antagonists). Since De Gasparo *et al.* does not specifically disclose the specific combination of telmisartan and simvastatin, it does not anticipate the instant claims. Accordingly, the anticipation rejection should be reconsidered and withdrawn.

The Examiner also rejected claims 1 and 8 to 35 as allegedly unpatentable under 35 U.S.C. § 103(a) over De Gasparo *et al.*, in light of Robl *et al.*, in view of Cecil's Textbook of Medicine (2000), Harlan *et al.* (U.S. Patent Appl. Pub. No. 2001/0006656), and Bohm *et al.* (WO 02/15891).

Applicants respectfully traverse the rejection. A *prima facie* case of obviousness generally requires the satisfaction of three criteria: (i) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings; (ii) there must be a reasonable expectation of success; and (iii) the references when combined must teach or suggest all of the claim limitations. *See* M.P.E.P. § 2143. As explained above, De Gasparo *et al.* does not disclose or suggest the specific combination of telmisartan and simvastatin

anywhere, nor does Robl *et al.*, Cecil's Textbook of Medicine, Harlan *et al.*, or Bohm *et al.* provide what De Gasparo *et al.* lacks in providing a motivation, reasonable expectation of success, or teaching or suggestion of all of the claim limitations of the claimed invention.

Furthermore, neither De Gasparo *et al.*, Robl *et al.*, Cecil's Textbook of Medicine, Harlan *et al.*, nor Bohm *et al.* teach or suggest that telmisartan increases the expression of genes regulated by the PPARgamma receptor, i.e., an activity known from antidiabetic drugs, which is the reason that telmisartan is a preferred combination partner for simvastatin in the treatment of, e.g., diabetes, and this metabolic activity appears to be unique for telmisartan and not recognized in the prior art. Indeed, De Gasparo *et al.* teaches the use of AT_1 receptor antagonists of "differing structural features" and therefore suggests that the specific chemical structure is of no concern and none of the other art cited makes up for this defect. Furthermore, neither Harlan *et al.* (disclosing an aerosol formulation of statins) nor Bohm *et al.* (disclosing a combination of telmisartan with ACE inhibitors) disclose, suggest, or hint at telmisartan combinations with statins and it is unclear why or how one of skill in the art at the time the claimed invention was made would combine their teachings with De Gasparo *et al.* Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this rejection.

The Examiner also provisionally rejected claims 1 and 8 to 35 for nonstatutory obviousness-type double patenting over claims 2 and 7 to 18 of U.S.S.N. 10/757,295, in view of Harlan *et al.*; provisionally rejected claims 1, 9 to 13, and 18 to 35 for nonstatutory obviousness-type double patenting over claims 1 to 10, 12 to 15, and 18 to 25 of U.S.S.N. 10/899,784; and provisionally rejected claims 1, 8, 14 to 19, and 21 to 35 for nonstatutory obviousness-type double patenting over claims 1 to 21 of U.S.S.N. 11/300,947 in view of Drug Facts and Comparisons (1996).

In response, applicants undertake to file a terminal disclaimer with respect to U.S.S.N. 10/757,295, U.S.S.N. 10/899,784, or U.S.S.N. 11/300,947, if (1) the instant claims be found otherwise allowable, and (2) applicants determine that such application poses a double patenting issue at that time. Accordingly, applicants respectfully request that the Examiner withdraw these provisional rejections for consideration later.

Applicants submit that all the pending claims are allowable and respectfully solicit a Notice of Allowance for all of the pending claims. If the Examiner feels that a telephone interview would be helpful in advancing prosecution of this application, the Examiner is invited to contact the attorney below.

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on May 7, 2007.

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